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Application No.: 10/724,010
Supplemental Information Disclosure Statement
PATENT

Practitioner's Docket No.

2960/116

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Berez et al.

Application No.: 10/724,010

Group No.: 3732

Filed: November 25, 2003

Examiner: Philogene, Pedro

For: **Patient Selectable Joint Arthroplasty Devices and Surgical Tools Facilitating Increased Accuracy, Speed and Simplicity in Performing Total and Partial Joint Arthroplasty**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
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**TRANSMITTAL OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
BEFORE MAILING DATE OF EITHER A FINAL ACTION
OR NOTICE OF ALLOWANCE (37 C.F.R. § 1.97(c))**

**TIME OF TRANSMITTAL OF ACCOMPANYING
INFORMATION DISCLOSURE STATEMENT**

1. The information disclosure statement transmitted herewith is being filed *after* three months of the filing date of this national application or the date of entry of the national stage as set forth in Section 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but *before* the mailing date of either

- (1) a final action under § 1.113 or
(2) a notice of allowance under § 1.311

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10*

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37 C.F.R. § 1.8(a)

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37 C.F.R. § 1.10*

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TRANSMISSION

☐ facsimile transmitted to the Patent and Trademark Office, (703) _____

Signature

Alexander J. Solenski, Jr., Esq.
(type or print name of person certifying)

Date: May 31, 2005

* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

whichever occurs first.

FEE

2. Accompanying this transmittal is the fee for submission of an information disclosure statement under section 1.97(c). (\$180.00)

FEE PAYMENT

3. Applicant elects the option to pay the fee set forth in 37 C.F.R. § 1.17(p) for submission of an information disclosure statement under § 1.97(c) (\$180.00).

Fee due \$180.00

METHOD OF PAYMENT OF FEE

4. Attached is a check in the amount of \$180.00.

Charge any additional fees required by this paper or credit to deposit account No. 19-4972.

A duplicate of this paper is attached.

DATE: May 31, 2005



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US

2960/116 388835



Practitioner's Docket No. 2960/116 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

of _____

Inventor(s)

for _____

Title of invention

the specification of which is being transmitted herewith OR

In re application of: Berez et al.

Application No.: 10/724,010

Group No.: 3732

Filed: November 25, 2003

Examiner: Philogene, Pedro

For: **Patient Selectable Joint Arthroplasty Devices and Surgical Tools Facilitating Increased Accuracy, Speed and Simplicity in Performing Total and Partial Joint Arthroplasty**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

(Information Disclosure Statement--page 1 of 15)

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

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Date: May 31, 2005

Signature

Alexander J. Smolenski, Jr., Esq.

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"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable C.F.R.e. requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

06/06/2005 SSESHE1 00000002 10724010 180.00 DP 01 FC:1806

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).

NOTE: The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

List of Sections Forming Part of This Supplemental Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: discard unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
 - 7A. ☐ JEPO Search Report
 - 7B. ☒ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections _____, respectively, have been continued on ADDED PAGE(S).

Application No. 10/724,010
Supplemental Information Disclosure Statement

NOTE : "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|-------------|--|------------------|------------------|
| Applicants: | Berez et al. | Attorney Docket: | 2960/116 |
| Serial No: | 10/724,010 | Art Group Unit: | 3732 |
| Date Filed: | November 25, 2003 | Examiner Name: | Philogene, Pedro |
| Invention: | Patient Selectable Joint Arthroplasty Devices and Surgical Tools Facilitating Increased Accuracy, Speed and Simplicity in Performing Total and Partial Joint Arthroplasty | | |

**LIST OF PATENTS AND PUBLICATIONS FOR
APPLICANT'S SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|------------------|-----------------|---------------------------------|------------------|----------------|
| Examiner Initials | Reference Number | Document Number | Issue Date/ Publication Date | Inventor | Class/Subclass |
| | AA | US 5,344,459 | Sep. 1994 | Swartz | 623/18 |
| | AB | US 5,827,289 | Oct. 1998 | Reiley et al. | 606/86 |
| | AC | US 6,328,765 | Dec. 2001 | Hardwick et al. | 623/23.72 |
| | AD | US 6,352,558 | Mar. 2002 | Spector, M. | 623/18.11 |
| | AE | US 6,358,253 | Mar. 2002 | Torrie et al. | 606/96 |
| | AF | US 6,375,658 | Apr. 2002 | Hangody et al. | 623/20.18 |
| | AG | US 6,443,988 | Sep. 2002 | Felt et al. | 623/17.12 |
| | AH | US 6,520,964 | Feb. 2003 | Tallarida et al. | 606/71 |
| | AI | US 6,632,235 | Oct. 2003 | Weikel et al. | 606/192 |
| | AJ | US 6,652,587 | Nov. 2003 | Felt et al. | 623/20.16 |
| | AK | US 6,679,917 | Jan. 2004 | Ek S. W. | 623/20.14 |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|------------------|-----------------|---------------------------------|-----------------|----------------|
| Examiner Initials | Reference Number | Document Number | Issue Date/ Publication Date | Inventor | Class/Subclass |
| | AL | US 2002/0059049 | May 2002 | Bradbury et al. | 703/111 |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|---------------------------------|-------------------------|---------------------|------------------------|-------------------------|------------------------------|-----------------------|
| Examiner Initials | Reference Number | Country Code | Document Number | Publication Date | Patentee or Applicant | Class/Subclass |
| | AM | WO | 93/25157 | Dec. 1993 | Rau et al. | A61B 17/56 |
| | AN | WO | 01/19254 | Mar. 2001 | Cummings et al. | A61B 17/00 |
| | AO | WO | 01/91672 | Dec. 2001 | Hanke, G. | A61F 2/36 |
| | AP | WO | 02/34310 | May 2002 | Dickson et al. | A61L 31/04 |
| | AQ | WO | 02/23483 | Mar. 2002 | Steines et al. | G06T 11/0 |
| | AR | WO | 04/043305 | May 2004 | Tsougarakis et al. | A61F 2/30 |
| | AS | EP | 0 626 156 | Jan. 1992 | Walker, P.S. | A61F 2/38 |

| OTHER DOCUMENTS | | | |
|--------------------------|-------------------------|---------------------|---|
| Examiner Initials | Reference Number | Author | Title of Article, Title of Journal, Volume Number, Page Numbers, Date |
| | AT | Taha et al. | "Modeling and design of a custom made cranium implant for large skull reconstruction before a tumor removal", Phidias Newsletter No. 6, pages 3-7, June 2001. Retrieved from the Internet: URL: http://www.materialise.com/medical/files/pdf |
| | AU | Kidder et al. | "3D model acquisition, design, planning and manufacturing of orthopaedic devices: a framework", Proceedings of the SPIE – Advanced Sensor and Control-System Interface, Boston, MA, Vol. 2911, pgs. 9-22, 21 November 1996 |
| | AV | Carr J.C. et al. | "Surface Interpolation with Radial Basis Functions for Medical Imaging", IEEE Transactions on Medical Imaging, IEEE, Inc., New York, Vol. 16, No. 1, 1 February 1997, pgs. 96-107 |
| | AW | C.S. Ranawat et al. | "MacIntosh Hemiarthroplasty in Rheumatoid Knee" Acta Orthop Belg. 1973 Jan-Feb: 39(1):102-112 |

OTHER DOCUMENTS (cont.)

| | | | |
|--|----|------------------------|--|
| | AX | B. Blum et al. | "Knee Arthroplasty in Patients with Rheumatoid Arthritis", Ann. Rheum. Dis. 1974 Jan: 33(1):1-11 |
| | AY | Nelson M.D. et al. | "Arthroplasty and Arthrodesis of the Knee Joint", Orthop. Clin. North Am. 1971 Mar: 2(1):245-264 |
| | AZ | McCollum et al. | "Tibial Plateau Prosthesis in Arthroplasty of the Knee", J. Bone Joint Surg. Am. 1970 Jun:52(4):827-828 |
| | BA | Hastings D.E. et al. | "Double Hemiarthroplasty of the Knee in Rheumatoid Arthritis. A Survey of Fifty Consecutive Cases", J. Bone Joint Surg. Br. 1973 Feb:55(1): pgs. 112-118 |
| | BB | Schron, D. et al. | "MacIntosh Arthroplasty in Rheumatoid Arthritis", Rheumatol Rehabil. 1978 Aug:17(3): pgs. 155-163 |
| | BC | McKeever, D. C. et al. | "The Classic Tibial Plateau Prosthesis", Clin Orthop. Relat. Res. 1985 Jan-Feb. (192):3-12 |
| | BD | Conaty et al. | "Surgery of the Hip and Knee in Patients with Rheumatoid Arthritis", J. Bone Joint Surg. Am. 1973 Mar:55(2): pgs. 301-314 |
| | BE | MacIntosh D. L. et al | "The Use of the Hemiarthroplasty Prosthesis for Advanced Osteoarthritis and Rheumatoid Arthritis of the Knee", J. of Bone & Joint Surg. 1972, Vol. 54B. No. 2, pgs. 244-255 |
| | BF | MacIntosh D.L. | "Arthroplasty of the Knee in Rheumatoid Arthritis Using the Hemiarthroplasty Prosthesis; Synovectomy and Arthroplasty in Rheumatoid Arthritis, pp. 79-80, Second Int'l. Symposium, Jan. 27-29, 1967 (Basle, Switzerland) |
| | BG | MacIntosh, D.L. | "Hemiarthroplasty of the Knee Using a Space Occupying Prosthesis for Painful Varus and Valgus Deformities", J. Bone Joint Surg. Am. 1958 Dec:40-A: pg. 1431 |
| | BH | Stauffer R. et al. | "The MacIntosh Prosthesis. Prospective Clinical and Gait Evaluation", Arch. Surg. 1975 Jun:110(6) pgs. 717-720 |
| | BI | Clary B. B. et al. | "Experience with the Use of the MacIntosh Knee Prosthesis", South Med. J. 1972 Mar:65(3) pgs. 265-272 |

OTHER DOCUMENTS (CONT.)

| | | | |
|--|-----------|-------------------------------|--|
| | BJ | Ghelman M.D. et al. | "Kinematics of the Knee After Prosthetic Replacements", Clin. Orthop. 1975 May: (108): pgs. 149-151 |
| | BK | Henderson, M.D. et al. | "Experience with the Use of the MacIntosh Prosthesis in Knees of Patients with Rheumatoid Arthritis", South. Med. J. 1969 Nov: 62(11) pgs. 1311-1315 |
| | BL | Potter M.D. | "Arthroplasty of the Knee with Tibial Metallic Implants of the McKeever and MacIntosh Design", Sug. Clin. North Am. 1969 Aug: 49(4) pgs. 903-915 |
| | BM | Potter T.A., et al. | "Arthroplasty of the Knee in Rheumatoid Arthritis and Osteoarthritis: A Follow-up Study After Implantation of the McKeever and MacIntosh Prostheses", J. Bone Joint Sug. Am. 1972 Jan: 54 (1) pgs. 1-24 |
| | BN | Bogoch, M.D. et al. | "Supracondylar Fractures of the Femur Adjacent to Resurfacing and MacIntosh Arthroplasties of the Knee in Patients with Rheumatoid Arthritis", Clin. Orthop. 1988 Apr. (229): pgs. 213-220 |
| | BO | Cameron et al. | "Review of a Failed Knee Replacement and Some Observations on the Design of a Knee Resurfacing Prosthesis", Arch. Orthop Trauma Surg. 1980: 97(2); pgs. 87-89 |
| | BP | Kates, A. et al. | "Experiences of Arthroplasty of the Rheumatoid Knee Using MacIntosh Prostheses", Ann. Rheum. Dis. 1969 May: 28(3) pg. 328 |
| | BQ | Jessop, J.D. et al. | "Follow-up of the MacIntosh Arthroplasty of the Knee Joint", Rheumatol Phys. Med. 1972 Feb: 11(5) pgs. 217-224 |
| | BR | Andersson, G.B. et al. | "MacIntosh Arthroplasty in Rheumatoid Arthritis", Acta. Orthop. Scand. 1974: 45 (2) pgs. 245-259 |
| | BS | Wordsworth, et al. | "MacIntosh Arthroplasty for the Rheumatoid Knee: A 10-year follow up", Ann. Rheum. Dis. 1985 Nov. 44(11) pgs. 738-741 |
| | BT | Kay, N.R. et al. | "The MacIntosh Tibial Plateau Hemiprosthesis for the Rheumatoid Knee", J. Bone Joint Surg., 1972 May, Vol. 54, No. 2, pgs. 256-262 |

OTHER DOCUMENTS (cont.)

| | | | |
|--|-----------|-----------------------------|---|
| | BU | Porter, M. L. et al. | "MacIntosh Arthroplasty: a long-term review", J.R. Coll. Surg. Edinb. 1988 Jan-Feb: (192); pgs. 199-201. |
| | BW | | International Search Report dated 23 February 2005. |
| | BV | | International Search Report dated 28 March 2005. |

Examiner Signature: _____

Date Considered: _____

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (i) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."

NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

☒ Exception(s) to above:

☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

U.S. patent citations are not included pursuant to the United State Patent and Trademarks Office's September 21, 2004 waiver of the copy requirement in 37 CFR 1.98 for cited pending U.S. patent citations when the patent citations are available in the USPTO's IFW system.

Section 7A. Concise Explanation of Non-English Language Listed Information Items—EPO Search Report

The relevance with respect to the following citations listed on Forms PTO/SB/08A and 08B (substitute for PTO-1449):

is submitted on the basis of the accompanying:

(check the appropriate item)

☒ EPO search report that is in the English language,

☐ EPO search report that is not in the English language and that is accompanied also by an English language version of the EPO search report,

that issued on the corresponding European patent application.

Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this certification is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (c) ☒ the practitioner who signs below on the basis of the information:

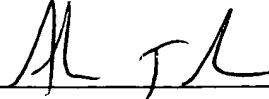
(check each applicable item)

☐ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).

☒ in the practitioner's file.

Application No. 10/724,010
Supplemental Information Disclosure Statement



SIGNATURE OF PRACTITIONER

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2960/116 388550